## 15. Ante/Post-partum Diseases

**Reference**

Fushiki H, Saeki A, Shiozaki A. Attempt to reduce adverse reactions associated with oral iron preparation for anemia in pregnancy by combination with rikkunshito (TJ-43)*. *Sanfujinka Kampo Kenkyu no Ayumi* (*Recent Progress of Kampo Medicine in Obstetrics and Gynecology*) 2003; 20: 138-9 (in Japanese). Ichushi Web ID: 2004068784

**1. Objectives**

To evaluate whether rikkunshito (六君子湯) combined with oral iron can improve hemoglobin level and reduce adverse reactions associated with the administration of iron for anemia in pregnant women.

**2. Design**

Randomized controlled trial (RCT).

**3. Setting**

One hospital (one obstetrics and gynecology clinic), Japan.

**4. Participants**

One hundred and twenty pregnant women (duration of pregnancy ≥ 5 months) with a hemoglobin (Hb) level of less than 11.0 g/dL, a hematocrit (Ht) of less than 33%, and a mean corpuscular volume (MCV) of less than 85 $\mu m^3$.

**5. Intervention**

Arm 1: treatment with sodium ferrous citrate (50 mg) 1 tablet b.i.d., and rikkunshito (六君子湯) 2.5 g t.i.d. for 14 days in patients with a mean age of 28.2 (20 - 42) years and a mean gestational age of 28.7 (18 - 38) weeks.

Arm 2: treatment with sodium ferrous citrate (50 mg) 1 tablet b.i.d. for 14 days in patients with a mean age of 28.8 (20 - 38) years and a mean gestational age of 28.4 (18 - 37) weeks.

**6. Main outcome measures**

Post-treatment Hb level.

**7. Main results**

Increase in Hb from the pre-treatment level was significantly greater after the sodium ferrous citrate plus rikkunshito therapy (arm 1; 0.8 [2.4 to -0.9] g/dL) than after sodium ferrous citrate monotherapy (arm 2; 0.3 [2.1 to -1.2] g/dL) ($P$=0.002). Also, oral administration of sodium ferrous citrate was better tolerated in arm 1.

**8. Conclusions**

It was suggested that rikkunshito combined with oral iron for anemia in pregnancy is effective for reducing adverse reactions associated with the administration of iron.

**9. From Kampo medicine perspective**

None.

**10. Safety assessment in the article**

There were no adverse reactions to rikkunshito treatment.

**11. Abstractor's comments**

Oral iron preparations are commonly associated with gastrointestinal adverse reactions. Thus, many patients stop the treatment. Great clinical relevance is suggested by the present results, which showed that treatment with iron could be continued in combination with rikkunshito. Although this study was classified as an RCT because of the random assignment, data necessary for the assessment of bias, including the presence or absence of blinding, were inadequate, and further assessment cannot be made. Further studies are expected.

**12. Abstractor and date**

Tsuruoka K, 15 June 2007, 1 April 2008, 1 June 2010, 31 December 2013.